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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/584,766 | 03/15/2007 | Stefan Beissert | 293024US0PCT | 5945 |
| 22850 | 7590 | 10/02/2008 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | HAMUD, FOZIA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 10/02/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/584,766 | Applicant(s) BEISSERT ET AL. | |
| | Examiner FOZIA M. HAMUD | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 24-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Requirement for Unity of Invention

Election/Restrictions

Status of Claims:

1. The preliminary amendments filed on 28 June 2006 and 13 August 2007 are acknowledged. Claims 1-23 have been cancelled and new claims 24-74 have been added. Thus, claims 24-74 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

2. This application is a 371 of PCT/EP04/13907, filed on 07 December 2004. For Applications filed under 371, PCT rules for lack of unity apply.

2a. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I Claims 24-59, 72-74 drawn (in part), to a method for
stimulating/treating hair growth comprising administering to a
subject a composition comprising the nucleic acid of SEQ ID NO:1
or nucleic acid encoding the polypeptide of SEQ ID NO:2.

Group II Claims 24-59, 72-74 , drawn (in part), to a method for
stimulating/treating hair growth comprising administering to a

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subject a composition comprising the nucleic acid of SEQ ID NO:3
or nucleic acid encoding the polypeptide of SEQ ID NO:4.

Group III Claims 24-59, 72-74 , drawn (in part), to a method for
stimulating/treating hair growth comprising administering to a
subject a composition comprising the polypeptide of SEQ ID NO:2.

Group IV Claims 24-59, 72-74, drawn (in part), to a method for stimulating
hair growth comprising administering to a subject a composition
comprising the polypeptide of SEQ ID NO:4.

Group V Claims 24-59, 72-74, drawn (in part), to a method for
stimulating/treating hair growth comprising administering to a
subject a composition comprising a compound which binds to an
antibody which specifically recognizes a polypeptide encoded by
the nucleic acid of SEQ ID NO:1.

Group VI Claims 24-59, 72-74, drawn (in part), to a method for
stimulating/treating hair growth comprising administering to a
subject a composition comprising a compound which specifically
binds to an IL-15 receptor alpha.

Group VII Claims 24-59, 72-74, drawn (in part), to a method for
stimulating/treating hair growth comprising administering to a
subject a composition comprising a compound which binds to an
antibody which specifically recognizes a polypeptide encoded by
the nucleic acid of SEQ ID NO:3.

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- Group VIII Claims 60-71 drawn (in part), to a transgenic non human animal comprising the nucleic acid of SEQ ID NO:1 or nucleic acid encoding the polypeptide of SEQ ID NO:2, and a method of stimulating hair growth in a non-human animal by transforming the animal with said nucleic acid.
- Group IX Claims 60-71 drawn (in part), to a transgenic non human animal comprising the nucleic acid of SEQ ID NO:3 or nucleic acid encoding the polypeptide of SEQ ID NO:4, and a method of stimulating hair growth in a non-human animal by transforming the animal with said nucleic acid.

Pursuant to 37 C.F.R. 1.475(d), this Authority considers that the main invention in the instant application comprises the first-recited method, namely a method for stimulating/treating hair growth comprising administering to a subject a composition comprising the nucleic acid of SEQ ID NO:1 or nucleic acid encoding the polypeptide of SEQ ID NO:2.

Further, pursuant to 37 C.F.R. 1.475(b)-(d), the ISA/US considers that the materially and functionally dissimilar methods of groups II-XIII, and the additional products of groups XIV-XV, do not correspond to the main invention. This Authority therefore considers that the several inventions do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single general inventive concept within the meaning of PCT Rule 13.1.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art by their recognized divergent subject matter as defined by MPEP § 1850. Therefore, an initial lack of unity for examination purposes as indicated is proper.

2b. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows: the second hair growth stimulating agents recited in claims 26 and 44. The species are independent or distinct because claims 26 and 44 recite second hair growth stimulating agents that are diverse in structure and function, for example cyclosporin, is an immunosuppressant drug widely used in post-allogeneic organ transplant, while potassium channel openers are compounds that cause local relaxation in smooth muscle by increasing membrane permeability to potassium ions. Thus, claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 25 and 43 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of

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search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FOZIA M. HAMUD whose telephone number is (571)272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
22 September 2008

/Bridget E Bunner/
Primary Examiner, Art Unit 1647